

## **REMARKS**

Claims 1-21 are currently pending in this application. Claims 6 and 11 have been amended. Claim 17 has been cancelled. Thus, after entry of this amendment, claims 1-16 and 18-21 remain pending in the present application.

### **Claim Rejections – 35 U.S.C. §§ 102 / 103**

Claims 1, 4-5, 11-12, and 16-17 were rejected under 35 U.S.C. § 102(b) as being anticipated by PCT Publication No. WO 01/62150 to Davison (“Davison”). Claims 1, 4, 11-12, and 16-17 were rejected under § 102(b) as being anticipated by U.S. Patent No. 6,306,152 to Verdonk et al. (“Verdonk”). Claims 2-3, 6-10, and 18-21 were rejected under 35 U.S.C. § 103(a) as being obvious over Davison in view of U.S. Patent No. 6,706,049 to Moerman (“Moerman”). Claims 2-3, 6-10, and 18-21 were rejected under § 103(a) as being obvious over Verdonk in view of Moerman. Claims 13-15 were rejected under § 103(a) as being obvious over Davison in view of U.S. Patent No. 6,332,871 to Douglas et al. (“Douglas”). Claims 13-15 were rejected under § 103(a) as being obvious over Verdonk in view of Douglas.

### **Independent Claim 1**

Independent claim 1 is directed to an endcap for a lancing device. The claimed endcap includes “a contact face on said body, the contact face having an inner portion and an outer portion” and “a plurality of ribs with channels defined between adjacent ribs, the plurality of ribs extending from the outer portion of the contact face toward the inner portion of the contact face.”

#### **1. Davison**

Davison is directed to a skin pricker having springs to project its tip through an aperture in a platform, which is pressed against a user’s skin. *See, e.g.*, Davison, Abstract. The skin pricker of Davison includes an array of circular studs on the platform and surrounding the aperture. *Id.*, FIG. 1.

Davison does not disclose, teach, or suggest “a plurality of ribs **with channels defined between adjacent ribs**,” as in claim 1. The illustrated embodiment of Davison includes twelve circular-shaped “cone studs” 4 abutting one another and surrounding the aperture 3. Davison, p. 2, ll. 14-15, 18. As noted by the Office Action, Davison discloses that “[c]oned studs appear to be effective, but other shapes such as serrations or elongate teeth arranged like the spokes of a wheel could work.” *See* Office Action, p. 2 (citing Davison, p. 1, ll. 25-27). Even though serrations or elongate teeth are mentioned in Davison, there is no disclosure of the claimed

“plurality of ribs extending from the outer portion of the contact face toward the inner portion of the contact face” of claim 1.

Furthermore, the only embodiment described in detail in Davison does not include any spacing between the cone studs. *See* Davison, FIG. 1. The advantages of the channels of claim 1 are described in the present specification:

The pattern of ribs 28 provide[s] pressure points on the skin around the puncture site while the gaps or channels 30 between the ribs 28 define areas of no pressure on the skin. These areas of no pressure act as channels under the skin for blood flow toward a puncture in the skin formed by the lance in the lancing device 10.

Present Spec., p. 5, ll. 9-13. Thus, Davison also does not disclose, teach, or suggest “a plurality of ribs **with channels defined between adjacent ribs**,” as in claim 1.

Thus, claim 1 is believed to be allowable over Davison. Moerman also does not cure these deficiencies in claim 1. Thus, claims 2-5, which depend on claim 1, are believed to be allowable for at least these reasons.

## **2. Verdonk**

Likewise, Verdonk fails to disclose, teach, or suggest all of the elements of claim 1. Verdonk discloses a skin-stabilizing end cap for increasing the tautness of the skin. *See, e.g.*, Verdonk, col. 3, ll. 46-48. By increasing the amount of skin held down by the end cap, the elastic limit of the skin upon impact with the lancet is reached more quickly, thereby causing a patient less pain. *Id.*, col. 5, ll. 58-64.

“[T]he plurality of legs 200 arranged in a ring-like fashion” of Figure 9 of Verdonk do not include “a plurality of ribs with channels defined between adjacent ribs.” *Id.*, col. 5, ll. 25-26. The legs of Figure 9, when applied to the skin, “will reduce the movement and increase the tautness of the skin in the vicinity”, and, thus, the legs do not form channels under the skin for blood to flow toward a puncture in the skin, as in the present invention. *Id.*, col. 5, ll. 28-29. Furthermore, Verdonk does not disclose “the contact face having an inner portion and an outer portion . . . the plurality of ribs extending from the outer portion of the contact face toward the inner portion of the contact face”. Moerman and Verdonk also do not cure these deficiencies.

Thus, claim 1 and its dependent claims, claims 2-5, are believed to be allowable for at least these reasons.

## **Dependent Claim 3**

Claim 3, which depends on claim 1, recites that the “contact face is concave.” The Office Action states that claim 3 is obvious over the combination of Davison and Moerman. Office Action, p. 6-7.

The Applicant submits that claim 3 is allowable for at least the reasons provided above with respect to claim 1, from which claim 3 depends. Furthermore, it would not have been obvious to combine Davison and Moerman, as suggested by the Office Action. *See* Office Action, pp. 6-7. For example, the cap of Moerman includes “a **radially inwardly** extending pressure-gradient.” Moerman, col. 2, ll. 31-32. The pressure-gradient “urges fluid to flow toward the opening.” *Id.*, col. 2, ll. 31-32. Thus, the cap of Moerman applies more pressure on the skin at an area having a greater distance from a puncture site than an area adjacent to the puncture site. The cap of Moerman only includes a depression (forming the pressure-gradient) but does not include any projections, protrusions, ribs, or the like. Thus, one skilled in the art would not be motivated to combine the skin pricker having abutting circular-shaped studs or “spoke-shaped” projections of Davison or the “plurality of legs” of Verdonk with Moerman’s concave face having a **depression** thereon.

### **Independent Claim 6**

As amended, independent claim 6 is directed to an endcap for a lancing device that includes “a body, said body including a face, an aperture in said face for passage of a lancet, said face being concave, and a rib pattern projecting from said face, said rib pattern including channels defined between adjacent ribs.”

Claim 6 is believed to be allowable for at least the same reasons provided above with respect to claim 1. Specifically, Davison, Moerman, and Verdonk do not disclose, teach, or suggest a “rib pattern including channels defined between adjacent ribs.”

Furthermore, as discussed above with respect to claim 3, it would not have been obvious to combine Davison and Moerman, as suggested by the Office Action. *See* Office Action, pp. 6-7. For example, the cap of Moerman includes “a **radially inwardly** extending pressure-gradient.” Moerman, col. 2, ll. 31-32. The pressure-gradient “urges fluid to flow toward the opening.” *Id.*, col. 2, ll. 31-32. Thus, the cap of Moerman applies more pressure on the skin at an area having a greater distance from a puncture site than an area adjacent to the puncture site. The cap of Moerman only includes a depression (forming the pressure-gradient) but does not include any projections, protrusions, ribs, or the like. Thus, one skilled in the art would not be

motivated to combine the skin pricker having abutting circular-shaped studs or “spoke-shaped” projections of Davison or the “plurality of legs” of Verdonk with Moerman’s concave face having a **depression** thereon.

Thus, claim 6 and claims 7-9, which depend on claim 6, are believed to be allowable for at least these reasons.

### **Independent Claim 11**

Amended claim 11 is directed to a method of drawing a blood sample for testing. The method includes “providing a lancing device having a lancet and an endcap, said endcap including a skin contacting face having an inner portion and an outer portion, the contacting face having a pattern of pressure points on said face, said pressure points comprising a plurality of ribs with **channels defined between adjacent ribs**, the plurality of ribs extending from the outer portion of the contacting face toward the inner portion of the contacting face” (emphasis added).

The Applicant respectfully submits that claim 11 and claims 12-21, which depend on claim 11, are allowable for at least the reasons set forth above with respect to claim 1.

Furthermore, claim 11 is not anticipated by Verdonk because Verdonk does not disclose, teach, or suggest “massaging said site with said skin contacting face on said site to cause blood to flow to said puncture”, as in claim 11. The Office Action mentioned column 5, lines 47-48 of Verdonk in an attempt to find this element in Verdonk. Office Action, p. 5. This applied portion of Verdonk, however, states, “The stressing and straining of the skin tissue continues to increase until the elastic limit of the skin has been reached.” Verdonk, col. 5, ll. 47-48. Such “stressing and straining” – which is performed to increase the tautness of the skin such that the elastic limit of the skin upon impact with the lancet is reached more quickly, thereby causing a patient less pain – is far different from the “massaging” of claim 11, which is performed “to cause blood to flow to the puncture where blood can be drawn and tested.” *See* Verdonk, *inter alia*, col. 3, ll. 46-48, col. 5, ll. 58-64; Present Spec., p. 5, ll. 17-18.

Thus, the Applicant submits that claim 11 is not anticipated by or rendered obvious over Davison or Verdonk for at least these reasons. Moerman and Douglas also do not cure these deficiencies. Thus, claim 11 and claims 12-16 and 18-21, which depend from claim 11, are believed to be allowable for at least these reasons.

## CONCLUSION

The Applicant submits that the claims are in a condition for allowance and action toward that end is earnestly solicited. It is believed that no fees are due; however, should any fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from the Nixon Peabody Deposit Account No. 50-4181 (247082-000077USPT).

Respectfully submitted,

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